K032991

SEP 1 4 2004

LIGHT AGE, INC.

510(k) Summary of Safety and Effectiveness
Light Age EpiCare™ Laser

In accordance with the Safe Medical Devices Act of 1990, 21CFR 807.92, the following is a summary of the safety and effectiveness information on which the substantial equivalence determination is based.

The safety and effectiveness of the Light Age EpiCare™ Laser derives from a determination of substantial equivalence to the predicate devices listed below.

Applicant: Light Age, Inc.
500 Apgar Dr.
Somerset, NJ 08873
Thomas C. Hauck, Manager of Quality and Process Technology

Date Prepared: Sept. 23, 2003

Description:

The Light Age EpiCare™ Alexandrite Laser has an Alexandrite crystal rod as a lasing medium. Pulsed energy is emitted at 755 nanometers in the near infrared portion of the spectrum. Energy from the laser is delivered to the target area via optical fiber with handpiece, which produces a circular beam on the skin. The EpiCare™ Alexandrite Laser is equipped with safety interlocks to protect patients and operators.

Intended Use:

The Light Age EpiCare™ Alexandrite Laser is indicated for permanent hair reduction, and the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

Model:

Trade Name: Light Age EpiCare™ Alexandrite Laser
Common Name: Pulsed Alexandrite Laser

Product Code: GEX

Panel: 79

C.F.R. Section: 878.4810

Classification Panel: General & Plastic Surgery

Classification:

Medical Device Class: Regulatory Class II

Laser Safety Class: Class IV Laser Product

Predicate Devices:

- Light Age™ EpiCare™ Alexandrite Laser (K983977)
- Candela™ GentleLASE Alexandrite Laser (K024260, K024335 & K024371)
- Cynosure™ Apogee-TKS Alexandrite Laser (K992757)
- Cynosure™ Apogee-TKS II Alexandrite Laser (K031488)
- Sharplan™ Model 5000 Alexandrite Laser (K971874 & K973354)
- Lumenis™ LightSheer™ Pulsed Diode Laser (K003614)

Description:

The Light Age EpiCare™ Alexandrite Laser has an Alexandrite crystal rod as a lasing medium. Pulsed energy is emitted at 755 nanometers in the near infrared portion of the spectrum. Energy from the laser is delivered to the target area via optical fiber with handpiece, which produces a circular beam on the skin. The EpiCare™ Alexandrite Laser is equipped with safety interlocks to protect patients and operators.

Intended Use:

The Light Age EpiCare™ Alexandrite Laser is indicated for permanent hair reduction, and the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

Safety and Effectiveness:

The Light Age EpiCare™ Alexandrite Laser has essentially the same wavelength, the same spot size, the same principle of operation, essentially the same fluence levels, and the same intended use as the predicate devices. The Light Age EpiCare™ Alexandrite Laser does not raise new questions of safety or efficacy, and is substantially equivalent to the predicate devices.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2004

Mr. Thomas C. Hauck
Manager of Quality and Process Technology
Light Age, Inc.
500 Apgar Drive
Somerset, New Jersey 08873

Re: K032991
Trade/Device Name: Light Age EpiCare™ Alexandrite Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 28, 2004
Received: July 29, 2004

Dear Mr. Hauck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

LIGHT AGE, INC.

Indications for Use

510(k) Number (if known): K032991

Device Name: Light Age EpiCare™ Alexandrite Laser

Indications For Use:

The Light Age EpiCare™ Alexandrite Laser is indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs re-growing after a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin.

It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

510(k) Number K032991